

**K161905 Disposable Circular Stapler for Hemorrhoids,  
Disposable Circular Stapler, Disposable Linear Stapler,  
Disposable Endoscopic Linear Cutter Stapler and Cartridge,  
Disposable Linear Cutter Stapler and Stapler Cartridge**Nov 17, 2016  
129 days to decisionK161905 · Product code: **GDW** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k161905/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Implantable (GDW)
Date received	Jul 11, 2016
Decision date	Nov 17, 2016
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Changzhou Xin Neng Yuan Medical Stapler Co.,Ltd</b>
Location	Changzhou, CN
Contact	Boping Ma
510(k) history	3 submissions · 3 cleared · 2016-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161905/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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